

117TH CONGRESS  
1ST SESSION

# H. R. 6160

To amend titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to provide for coverage of certain drugs used in the treatment or management of a rare disease or condition, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 7, 2021

Ms. MATSUI (for herself, Mr. THOMPSON of California, Mr. MULLIN, and Mr. KELLY of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to provide for coverage of certain drugs used in the treatment or management of a rare disease or condition, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Access to Rare Indica-  
5 tions Act of 2021”.

1 **SEC. 2. COVERAGE OF CERTAIN DRUGS USED IN TREAT-**  
2 **MENT OR MANAGEMENT OF RARE DISEASE**  
3 **OR CONDITION.**

4 (a) **MEDICARE.**—

5 (1) **IN GENERAL.**—Section 1861(t)(2) of the  
6 Social Security Act (42 U.S.C. 1395x(t)(2)) is  
7 amended—

8 (A) in subparagraph (A), by inserting after  
9 “regimen” the following: “, or in the treatment  
10 or management of a disease or condition affect-  
11 ing 200,000 or fewer individuals in the United  
12 States,”; and

13 (B) in subparagraph (B)(ii)—

14 (i) in subclause (I), by striking “, or”  
15 at the end and inserting a semicolon;

16 (ii) in subclause (II), by striking the  
17 period at the end and inserting “; or”; and

18 (iii) by adding at the end the fol-  
19 lowing new subclause:

20 “(III) in the case of a drug that  
21 is used in the treatment or manage-  
22 ment of a disease or condition affect-  
23 ing 200,000 or fewer individuals in  
24 the United States, such use is sup-  
25 ported by peer-reviewed medical lit-  
26 erature, clinical guidelines, or an ex-

1           pert in such disease or condition as  
2           identified by a medical society in-  
3           volved in the treatment or manage-  
4           ment of such disease or condition, and  
5           is not reviewed unfavorably in the  
6           compendia described in section  
7           1927(g)(1)(B)(i), or listed as a con-  
8           traindication in the FDA-approved la-  
9           beling.”.

10           (2) MEDICALLY ACCEPTED USES OF COVERED  
11           PART D DRUGS IN TREATING RARE CONDITIONS.—  
12           Section 1860D–2(e)(4)(A) of the Social Security Act  
13           (42 U.S.C. 1395w–104(e)(4)(A)) is amended—

14                   (A) in clause (i)(II), by striking “and”;

15                   (B) by redesignating clause (ii) as clause  
16           (iii); and

17                   (C) by inserting after clause (i)(II) the fol-  
18           lowing new clause:

19                   “(ii) in the case of a covered part D  
20           drug used in the treatment or management  
21           of a disease or condition affecting 200,000  
22           or fewer individuals in the United States,  
23           in section 1861(t)(2)(B); and”.

24           (3) EFFECTIVE DATE.—The amendments made  
25           by this subsection apply with respect to items and

1 services furnished on or after the date that is 30  
2 days after the date of the enactment of this Act.

3 (b) MEDICAID.—

4 (1) IN GENERAL.—Section 1927(k)(6) of the  
5 Social Security Act (42 U.S.C. 1396r–8(k)(6)) is  
6 amended to read as follows:

7 “(6) MEDICALLY ACCEPTED INDICATION.—The  
8 term ‘medically accepted indication’ means any use  
9 for a covered drug—

10 “(A) which is approved under the Federal  
11 Food, Drug, and Cosmetic Act;

12 “(B) which is supported by one or more ci-  
13 tations included or approved for inclusion in  
14 any of the compendia described in subsection  
15 (g)(1)(B)(i); or

16 “(C) in the case of a drug used to treat or  
17 manage a disease or condition affecting  
18 200,000 or fewer individuals in the United  
19 States—

20 “(i) the use of such drug is supported  
21 by peer-reviewed medical literature, clinical  
22 guidelines, or an expert in such disease or  
23 condition as identified by a medical society  
24 involved in the treatment or management  
25 of such disease or condition; and



1           “(1) approved by the Food and Drug Adminis-  
2           tration;

3           “(2) for which the use is related to treatment  
4           or management of a disease or condition affecting  
5           200,000 or fewer individuals in the United States;  
6           and

7           “(3) the use of which is supported by the FDA-  
8           approved label, peer-reviewed literature, clinical  
9           guidelines, or an expert in such disease or condition  
10          as identified by a medical society involved in the  
11          treatment or management of such disease or condi-  
12          tion, and that is not reviewed unfavorably in the  
13          compendia described in section 1927(g)(1)(B)(i) of  
14          the Social Security Act or listed as a contraindica-  
15          tion in the FDA-approved labeling.”.

16          (2) EFFECTIVE DATE.—The amendment made  
17          by this subsection applies with respect to plan years  
18          beginning on or after the date that is 30 days after  
19          the date of the enactment of this Act.

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